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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/811,542

03/29/2004

Gerald D. Buckberg

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7590

05/01/2006

PROCOPIO, CORY, HARGREAVES & SAVITCH LLP

530 B STREET

SUITE 2100

SAN DIEGO, CA 92101

EXAMINER

CHATTOPADHYAY, URMI

ART UNIT

PAPER NUMBER

3738

DATE MAILED: 05/01/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

10/811,542

Applicant(s)

BUCKBERG ET AL.

Examiner

Urmi Chattopadhyay

Art Unit

3738

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 29 March 2004.  
2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.  
3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 7-24 is/are pending in the application.  
4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.  
5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.  
6) ☒ Claim(s) 7-12 and 14-24 is/are rejected.  
7) ☒ Claim(s) 13 is/are objected to.  
8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☒ The specification is objected to by the Examiner.  
10) ☒ The drawing(s) filed on 29 March 2004 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).  
11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some \* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)  
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)  
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date 3/29/04.  
4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_  
5) ☐ Notice of Informal Patent Application (PTO-152)  
6) ☐ Other: \_\_\_\_\_

## **DETAILED ACTION**

### ***Response to Amendment***

1. The preliminary amendment filed March 29, 2004 has been entered. The changes to the specification and title have been approved. Claims 1-6 have been canceled and new claims 7-24 have been added. The new claims 7-15 added and changes made to the specification in another preliminary amendment (originally filed in a continuing application of 09/689,254) also filed March 29, 2004 have not been entered because replacement paragraphs with markings to show changes have not been presented.
2. The new paragraph regarding cross-reference to related applications must be updated to indicate that 10/216,348 is now abandoned.

### ***Priority***

3. The claims receive benefit of parent application 09/235,664, and therefore have an effective filing date of January 22, 1999.

### ***Drawings***

4. The drawings are objected to as failing to comply with 37 CFR 1.84(p)(5) because they do not include the following reference sign(s) mentioned in the description: "lines 10-10" mentioned on page 10, line 9 is not shown in Figure 9; "inferior wall 44" mentioned on at least page 13, line 24 is not shown in the figures; "base suture 143" mentioned on lines 4-5 of the amended paragraph on page 27 is not shown in the figures. Corrected drawing sheets in

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compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

5. The drawings are objected to because based on the amended paragraph on page 21, "90" in Fig. 12B should be changed to --89--; "89" in Fig. 13 should be changed to --90-- for tubular sheath; "95" in Fig. 22A should be changed to --89-- for concave surface rather than convex surface. Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will

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be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

6. The drawings are objected to as failing to comply with 37 CFR 1.84(p)(5) because they include the following reference character(s) not mentioned in the description: "107" in Figs. 21 and 22A and "6" in Fig. 30 are not mentioned in the specification. Corrected drawing sheets in compliance with 37 CFR 1.121(d), or amendment to the specification to add the reference character(s) in the description in compliance with 37 CFR 1.121(b) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

### *Specification*

7. The disclosure is objected to because of the following informalities:
- a) On page 2, line 21, "sternum" should be changed to --septum--.
  - b) On page 5, line 11, "lung congestive" should be changed to --lung congestion--.
  - c) On page 12, line 24, "which" should be changed to --and--.
  - d) On page 15, lines 13 and 23, it appears from Fig. 2 that "50" should be --58--.
  - e) On page 16, line 13, "infraction" should be changed to --infarction--.

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- f) On page 18, line 16, "infraction" should be changed to --infarction--.
  - g) On line 1 of the amended paragraph on page 21, "fiat" should be changed to --flat--.
  - h) On page 22, line 14, it appears that "claim 18" should be --Figures 16 and 18--.
  - i) On page 23, line 2, "patch 82" should be changed to --patch 72--.
  - j) On page 23, line 15, it appears that "Figure 51" should be changed to --Figure 21--.
  - k) On line 2 of the amended paragraph on page 23, "neck 87" should be --neck 78--.
  - l) On page 24, line 8, "suture 112" should be changed to --suture 105--.
  - m) On page 24, lines 14-15, "septum over the wall 41 ventricular wall 38" should be changed to --septum wall 41 over the ventricular wall 38--.
  - n) On page 26, line 10, "advantages" should be changed to --advantage--.
  - o) On page 26, line 12, "value" should be changed to --valve--.
  - p) On page 26, line 12, it appears that "intra-aortic" should be changed to --intra-atrial--.
  - q) On page 26, line 19, "patch 70" should be changed to --patch 72--.
  - r) On line 7 of the amended paragraph on page 27, it appears from Fig. 27 that "pledgets 157 and 160" should be changed to --pledgets 151 and 160--.
  - s) On line 6 of the amended paragraph on page 27, "pledgits" should be --pledgets--.
  - t) On line 7 of the amended paragraph on page 27, "an" should be changed to --a--.
- Appropriate correction is required.

### *Claim Objections*

- 8. Claims 13 and 23 objected to because of the following informalities:
  - a) Claim 13, one of the two periods at the end of the claim should be deleted.

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b) Claim 23 is the same as claim 22; claim 23 should be canceled.

Appropriate correction is required.

***Claim Rejections - 35 USC § 112***

9. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 16-24 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

10. Claims 16 and 21 both require the patch to include "a sheet of biocompatible material with a continuous ring fixed to the sheet in the shape of a triangle". It is unclear whether the biocompatible material or the ring is being limited to a triangular shape. Grammatically, the sheet is being limited because it is directly preceding "in the shape of a triangle". However, dependent claims 20 and 24 limit the sheet of the biocompatible material to a triangular shape. For examination purposes, the claims will be interpreted such that the continuous ring is in the shape of a triangle. The examiner suggests rewording the limitation in claims 16 and 21 to --patch including a sheet of biocompatible material with a continuous ring in the shape of a triangle fixed to the sheet--.

***Claim Rejections - 35 USC § 103***

11. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

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(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

12. Claims 7-11, 15-17 and 20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Dor (*"Left Ventricular Aneurysms: The Endoventricular Circular Patch Plasty"*, as cited in applicant's IDS) in view of Alferness (USPN 5,702,343 as cited in applicant's IDS).

Dor discloses method for restoring the ventricular architecture of a heart having an anterior wall and an inferior wall with all the elements of claims 7 and 16, but is silent to the limitations of a triangular continuous ring being fixed to the sheet, as required by claims 7 and 16, and sewing the continuous ring to the inner surface of the inferior wall along the suture line to restore the ventricular architecture of the heart, as further required by claim 7. See Figure 1 for creating an incision in the inferior wall of the heart to expose an inner surface of the ventricle. See Figure 2 for forming a suture line around the inner surface of the inferior wall. See Figure 5 for providing a ventricular patch having a sheet of biocompatible material. Alferness teaches a cardiac reinforcement patch in Figure 1 for locally constraining cardiac expansion (column 1, lines 63-65) including a continuous sewing ring (3) fixed to the sheet of biocompatible material (2) in order to reinforce the patch for attachment by sutures of the patch to the heart, thereby restoring the ventricular architecture of the heart. See column 3, lines 39-62 and column 6, lines 13-28. It would have been obvious to one of ordinary skill in the art at the time of applicant's invention to look to the teachings of Alferness to modify the triangular patch of Dor by including a continuous sewing ring in order to reinforce the patch for attachment by sutures of the patch to the heart. Because the ring is attached to the peripheral edge (4) of the patch, the shape of the ring will reflect the shape of the patch. Therefore, including a ring to the



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peripheral edge of the patch of Dor will mean that the ring is triangular in shape. Also, because the periphery of the patch of Dor is sewn to the inner surface of the inferior wall along the suture line to restore the ventricular architecture of the heart, the inclusion of the peripheral ring will mean that the ring will be sewn to inner surface of the inferior wall along the suture line.

Claim 8, see abstract and the second paragraph in the second column of page 124 for creating an incision in the non-contracting region of the inferior wall and Figure 1 for opening the incision to expose an inner surface of the heart.

Claim 9, see abstract and the third paragraph in the second column of page 124 and Figure 2 for forming a suture line generally along the line of separation.

Claim 10, see Figure 5 for spreading the incision to create a triangular opening extending into the ventricle of the heart.

Claims 11 and 17, see Figure 5. The outer rim of the patch is interpreted as the portion of the biocompatible material to which the continuous ring is fixed. Because the continuous ring has a constant width, the outer rim of the patch will have a constant width around the central area of the patch.

Claims 15 and 20, see Figure 5 for the sheet of biocompatible material being in the shape of a triangle.

13. Claims 12, 14, 18 and 19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Dor and Alferness as applied to claims 7 and 16 above, and further in view of Kugel (USPN 5,634,931).

Dor, as modified by Alferness, discloses a method for restoring the ventricular architecture of a heart having an anterior wall and an inferior wall with all the elements of claims 7 and 16, including the ring defining a central area of the patch inwardly of the ring, but is silent to the ring defining an outer rim of the patch outwardly of the ring, as required by claims 12 and 18. Kugel teaches a patch including a sheet of biocompatible material and a continuous ring fixed thereto, wherein the ring defines an outer rim having a generally constant width (claims 14 and 19) of the patch outwardly of the ring in order to for the outer rim to provide as an apron to fill in uneven voids in the patient's tissue. See column 7, lines 51-56. It would have been obvious to one of ordinary skill in the art at the time of applicant's invention to look to the teachings of Kugel to modify the ventricular patch of Dor and Alferness by having the reinforcing sewing ring define an outer rim of constant width of the patch outwardly of the ring in order for the outer rim to provide as an apron to fill in uneven voids in the patient's tissue. By filling in the voids, the examiner contends that blood leakage will be by nature advantageously reduced.

*Allowable Subject Matter*

14. Claim 13 objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims, and overcoming the claim objection.

15. Claim 21 would be allowable if rewritten or amended to overcome the rejection(s) under 35 U.S.C. 112, 2nd paragraph, set forth in this Office action.

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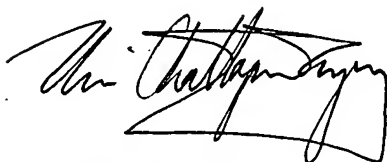
16. Claims 22 and 24 would be allowable if rewritten to overcome the rejection(s) under 35 U.S.C. 112, 2nd paragraph, set forth in this Office action and to include all of the limitations of the base claim and any intervening claims.

17. Claim 23 would be allowable if rewritten to overcome the objection and rejection(s) under 35 U.S.C. 112, 2nd paragraph, set forth in this Office action and to include all of the limitations of the base claim and any intervening claims.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Urmi Chattopadhyay whose telephone number is (571) 272-4748. The examiner can normally be reached Monday through Thursday and every other Friday from 9:00am to 6:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott can be reached at (571) 272-4754. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Urmi Chattopadhyay

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